K093399

INRAD®

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Contact Information
Melissa Lalomia
Director of Quality & Regulatory Affairs
Phone: 616-301-7800, ext. 102
Fax: 616-301-7799
E-mail: mlalomia@inrad-inc.com

Company Information
Inrad, Inc
4375 Donker Court SE
Kentwood, MI 49512
Phone: 616-301-7800
Fax: 616-301-7799

Device Name(s)
PreciseCore™ Biopsy Device

Device Summary

Trade or Proprietary Name:	PreciseCore™ Biopsy Device
Common or Usual Name:	Biopsy Instrument
Classification Name:	Gastroenterology-urology biopsy instrument (21 CFR 876.1075, Product code KNW)

Name of Predicate(s) or Legally Marketed Device(s)
K994272 – Promex Automated Core Biopsy Device
Also known as:
- SABD™ Disposable Core Biopsy System(US Biopsy is a division of Promex Technologies)
- Inrad® AccuCore Single Action Core Biopsy Device (manufactured for Inrad by US Biopsy)

Device Description

The PreciseCore™ Biopsy Device is a sterile, disposable device which features a stainless steel cutting cannula and stylet. The device is comprised of a plastic housing that contains the mechanically actuated components. The stylet of the device is stationary, therefore acquiring tissue without an advancement of the needle set beyond the visualized tip.

Indications for Use

The device is intended for use in obtaining biopsies from soft tissues such as liver, breast, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. For breast biopsy this product is for diagnosis only – not for therapeutic use.

Substantial Equivalence

The PreciseCore™ Biopsy Device has the same intended use as the Inrad® AccuCore Single Action Core Biopsy Device and US Biopsy SABD. The device and the predicate devices have the same technological characteristics in terms of design and materials.

Performance Testing Summary

Performance testing confirms that the quality of samples obtained with the PreciseCore™ Biopsy Device is equivalent to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Inrad, Inc.
% Ms. Melissa Lalomia
Director of Quality and
Regulatory Affairs
4375 Donker Court SE
Kentwood, Michigan 49512

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Re: K093399
Trade/Device Name: PreciseCore™ Biopsy Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: October 28, 2009
Received: November 2, 2009

Dear Ms. Lalomia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093399

Device Name: PreciseCore™ Biopsy Device

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for a xxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093399